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## REMARKS

Reconsideration of the Final Rejection is respectfully requested.

Claims 49, 55, 57, 58, 62, 63, 70, 85 and 88-90 have been withdrawn from consideration as being drawn to non-elected species. Reconsideration of the withdrawal from consideration of these claims is respectfully requested. Each of Claims 49, 55, 57, 58, 62, 63, 70, 85 and 88-90 depends on a linking claim, which is generic thereto. If a linking claim is allowed, the Examiner must examine species linked thereto, [MPEP 809.04]. Accordingly, where the Examiner's reconsideration of the linking claims finds them to be patentable, withdrawal of the non-elected species should be considered.

Claims 56, 75 and 84 have been rejected under 35 USC 112 as being indefinite. The Claims as presently presented are amended in accordance with the Examiner's comments and are believed to comply with 35 USC 112.

Beneficially, Applicant's invention provides consumers who have a specified discomfort with relief for the discomfort and indications of one or more nutritional supplements for supplementing nutrition. This enables them to self-regulate their consumption of nutritional supplements while relieving their discomfort. Applicant's invention saves consumers the additional cost, time and storage space needed for purchase and use of the separately enclosed discomfort relievers and nutritional supplements for supplementing nutrition of the prior art.

### **MAJOR COMMERCIAL DISCOMFORT RELIEVERS WITH MINERALS DO NOT HAVE INDICATIONS FOR SUPPLEMENTING NUTRITION**

Major commercial pain relievers include mineral(s): iron, magnesium and/or calcium, and indicate them as being inert ingredients and/or buffering agents. But they do not provide an indication of the amount of the mineral(s) per unit dose, an indication of their percent daily value per unit dose, or an indication that these mineral(s) are provided to supplement nutrition. For example, Advil pain reliever packaging (EXHIBIT A) and Motrin pain reliever packaging (EXHIBIT B), both indicate iron as an inert ingredient. As pain reliever they each indicate ibuprofen. Similarly, Aleve, Tylenol and Excedrin each indicates

magnesium as an inert ingredient. Aleve pain reliever packaging (EXHIBIT C) and information sheet (EXHIBIT D) indicate naproxin as pain reliever. While Tylenol pain reliever packaging (EXHIBIT E) and Excedrin pain reliever packaging (EXHIBIT F) both indicate acetaminophen as pain reliever [Excedrin also indicates caffeine as pain reliever.] Additionally, Bufferin pain reliever packaging (EXHIBIT G) indicates calcium and magnesium carbonates as buffering agents, and magnesium as an inactive ingredient. Aspirin is indicated as pain reliever. Thus, these major commercial pain relievers include mineral(s) but do not indicate them as supplementing nutrition. The Examiner states that the law mandates the inclusion of indications, (pages 5, 6, 7 and 8 of the Final Rejection). Yet these major commercial pain relievers do not include indications of minerals supplementing nutrition. Thus, the law has not made necessary the inclusion of indications for supplementing nutrition by minerals in major commercial pain relievers. Like mineral inert ingredients and mineral buffering agents, vitamin antioxidants in prior art pain relievers would not be indicated as supplementing nutrition.

The Examiner states that the ultimate function of the instant composition relies on the active ingredients: ibuprofen and vitamin C (page 8 of the Final Rejection). Vitamin C is included (as an ingredient) to function as part of a discomfort reliever, in the applied prior art. It reduces oxidation as see Yeh et al column 2, lines 31-37. Vitamin C is not provided to function by supplementing nutrition in the applied prior art. So, vitamin C would not be indicated as a nutritional supplement in the applied prior art, just as minerals are not indicated as nutritional supplements in major commercial pain relievers, as discussed above.

The Examiner states that the identical chemical composition cannot have mutually exclusive properties, and vitamin C functions as nutritional supplement regardless of whether the prior art teaches so, (pages 9 and 10 of the Final Rejection). However, Applicant does not claim a chemical composition, but a method of indication for supplementing nutrition. Indications (of Applicant's invention) indicate the nutrition supplementing

function of the unit dose of the discomfort relieving composition. Vitamin C in the applied prior art discomfort relievers, is provided as part of a composition for discomfort relief, and not for supplementing nutrition. Thus, vitamin C would not be indicated for supplementing nutrition just as mineral inert ingredients and/or mineral buffering agents are not indicated as supplementing nutrition in major commercial pain relievers.

The Examiner states that it is unclear how the disclosure in Yeh et al of antioxidant vitamin C as part of a pain reliever essentially teaches away from the invention, (page 9 of the Final Rejection). Yeh et al teach that an antioxidant other than a vitamin (A, C or E) may be used (column 2, lines 48-52). Thus, Yeh et al do not teach that vitamin C (or anything else) is provided to supplement nutrition. So, Yeh et al teach away from the invention by teaching that the lack of anything that could function as a nutritional supplement is suitable for its purposes. Accordingly, no indication of supplementing nutrition would be provided for antioxidant and/or synergistic vitamin C as part of a pain reliever, just as mineral inert ingredients and/or mineral buffering agents are not indicated as supplementing nutrition in major commercial pain relievers.

The Examiner states that a reconstruction is proper if it takes into account only knowledge, which was within the ordinary skill at the time of the invention, and does not include knowledge gleaned from Applicant's disclosure, (page 7 of the Final Rejection). However, the reconstruction is insufficient as it omits features of the invention, when it takes into account only knowledge, which was within the ordinary skill at the time of the invention. More specifically, nowhere in any of the prior art references is there any suggestion to provide a unit dose of discomfort reliever with indications indicating supplementing nutrition.

The Examiner states that the indications are not functionally related to the composition, and that printed material does not patentably distinguish over the prior art, (pages 8-9 of the Final Rejection). But, indications of Applicant's invention indicate the nutrition supplementing function of the unit dose of the discomfort relieving composition. The prior art does not indicate this function,

just as mineral inert ingredients and/or mineral buffering agents are not indicated as supplementing nutrition in major commercial pain relievers.

The fact that printed matter by itself is not patentable subject matter, because non-statutory, is no reason for ignoring it when the claim is directed to a combination, Application of Miller 164 USPQ 46 (CCPA 1969). Applicant's claimed method combines indications indicating supplementing nutrition with a unit dose of discomfort reliever in an enclosure. Thus, the claim recitation of indications indicating supplementing nutrition combined with a unit dose of discomfort reliever in an enclosure may not be ignored, Application of Miller.

Additionally, the Court stated that one gives printed matter patentable weight if it is functionally related to the substrate, and the court found that printed matter (numbers) did bear a presumptively new and unobvious functional relation to the substrate, In re Gulack 703 F.2d 1381, 217 USPQ 401 (CAFC, 1983). Applicant's invention provides indications indicating the nutrition supplementing function of the unit dose of the discomfort relieving composition. The prior art does not indicate this function. So, indications indicating supplementing nutrition should be given patentable weight as they are functionally related to the unit dose of the discomfort reliever in the enclosure. Furthermore, Applicant's invention educates the user of the nutrition supplementing function of the unit dose of discomfort reliever, which is a basis for patentability In re Gulack. The court has cautioned against liberal use of printed matter rejections, In re Lowry 32 F.3d 1579, 32 USPQ 2d 1031 (CAFC, 1994). As part of its burden to establish a prima facie case of obviousness, the burden of establishing the absence of a novel, nonobvious functional relationship rests with the PTO. The PTO must establish this within the context of the entire claims, In re Lowry. The Examiner has not established the absence of a novel, nonobvious functional relationship between indications indicating supplementing nutrition and a unit dose of discomfort reliever in an enclosure.

The Examiner states that one cannot show nonobviousness by attacking references individually where the rejection is based on a combination of references, In re Keller, 642 F.2d 413, 425, 208 USPQ 871

881 (CCPA 1981) and In re Merck & Co. 231 USPQ 375, 380 (CAFC, 1986) (page 6 of the Final Rejection). While the test for obviousness is what the combined teachings of the references would have suggested to those of ordinary skill in the art, In re Keller. The combination of references is improper because it lacks a basis for combining the teachings of the references, In re Sernaker 702 F2d 989, 217 U.S.P.Q. 1 (CAFC, 1983).

#### LACK OF ANY TEACHING FOR THE COMBINATION OF REFERENCES

Claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69, 71-84, 86-87 and 91-94 have been rejected under 35 USC 103 as being unpatentable over SS Pharmaceutical, Tsunoda, Yeh et al in view of Krause. Beneficially, Applicant's invention provides a unit dose of discomfort reliever in an enclosure having indications indicating supplementing nutrition. For example, the enclosure may have indications indicating a nutritional supplement for supplementing nutrition, a percent of a daily value for a nutritional supplement and/or instructions for consuming the unit dose for supplementing nutrition. A proper combination of references requires a teaching in the references to suggest the combination thereof, In re Sernaker 702 F2d 989, 217 U.S.P.Q. 1 (CAFC, 1983), and cannot be based on forbidden hindsight, In re Rouffet 47 USPQ2d 1453, 1458 (CAFC, 1998). SS Pharmaceutical, and Tsunoda, and Yeh et al disclose pharmaceutical medication (cold, menstruation and/or periodontal). The Examiner states that Krause discloses food product labeling. Pharmaceutical medication (cold, menstruation and/or periodontal) is not disclosed by Krause. Neither food, food product labeling, nutrition nor supplementing nutrition is disclosed by SS Pharmaceutical, Tsunoda, or Yeh et al. There is no teaching in SS Pharmaceutical, Tsunoda, Yeh et al or Krause to suggest the combination thereof to provide the method claimed by Applicant. This lack of a showing of motivation for combining references cited in the rejection is clear error, In re Sernaker, and is based on forbidden hindsight, In re Rouffet. Accordingly, the combination of SS Pharmaceutical, Tsunoda, Yeh et al and Krause is clearly improper.

## THE COMBINATION OF REFERENCES IS A HINDSIGHT RECONSTRUCTION OF APPELLANT'S INVENTION

A problem with the rejection is that nowhere in any reference is there any suggestion to provide a unit dose of discomfort reliever (with or without an antioxidant and synergistic part of the discomfort reliever) with indications indicating supplementing nutrition. Beneficially, Applicant's invention provides a unit dose of discomfort reliever in an enclosure having indications indicating supplementing nutrition. For example, the enclosure may have indications indicating a nutritional supplement for supplementing nutrition; a percent of a daily value for a nutritional supplement in the unit dose and/or instructions for consuming the unit dose for supplementing nutrition. To say that this would have been obvious is to resort to impermissible hindsight, In re Marshall 198 USPQ 344 at 346-347 (CCPA, 1978).

Cold medication in SS Pharmaceutical, menstruation medication in Tsunoda, periodontal medication in Yeh et al and food labeling in Krause are isolated disclosures. One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention, In re Fine, 837 F2d 1071, 1075, 5 USPQ 2d 1598, 1600 (Fed. Cir. 1988). The Examiner has picked and chosen among isolated disclosures in the prior art for medication, and isolated disclosures in the prior art for food labeling. It is legal error to use the inventor's patent specification teaching of both a novel and nonobvious invention as though it were prior art in order to make claims appear to be obvious In re Pleuddemann, 901 F2d 823, 828, 15 USPQ 2d 1738, 1742 (Fed. Cir 1990). In constructing the rejection the Examiner combines SS Pharmaceutical, Tsunoda, Yeh et al and Krause without any teaching in the references for the combination thereof. The Examiner has made legally erroneous use of the inventor's patent specification teaching of both a novel and nonobvious invention as though it were prior art in order to make claims appear to be obvious In re Pleuddemann. So, the combination of SS Pharmaceutical, Tsunoda, Yeh et al and Krause of the rejection is legal error.

## SUPERIOR RESULTS

Benefits provided by the invention claimed in the above captioned patent application, which are not provided by the applied prior art include: a unit dose of discomfort reliever in an enclosure having indications indicating a percent daily value for nutritional supplement in a unit dose of discomfort reliever. A practical significance of Applicant's invention, compared to the applied prior art, is that the user has discomfort relief and an indication of a percent daily value for the nutritional supplement in each unit dose. With this indication the user has the ability to self regulate consumption of nutritional supplements while alleviating a discomfort. This is a superior result. The statute does not require a patentable invention to be superior Demaco Corp v F Von Langsdorff Licensing Ltd. 7 USPQ2d 1222 (Fed. Cir 1988).

Applicant's claimed invention provides superior results by relieving discomfort and indicating a percent daily value for a nutritional supplement in each unit dose thereby providing the ability to self regulate nutritional benefits while alleviating a discomfort. Accordingly, the rejection of the claims as being unpatentable over SS Pharmaceutical, Tsunoda, Yeh et al and Krause is improper. Patentability is shown beyond the requirements of the statute, Demaco.

The Examiner states that the indications that provide the superior results are expected because the law requires them (page 8 of the Final Rejection). But major commercial pain relievers do not include such indications for mineral inert ingredients and/or mineral buffering agents, as discussed above. Thus, the law has not made necessary the inclusion of these indications for mineral inert ingredients and/or mineral buffering agents. Like minerals, vitamin antioxidants would not be indicated as supplementing nutrition in the applied prior art.

## THE APPLIED REFERENCES TEACH AWAY FROM THE INVENTION

The Examiner states that it is unclear how the disclosure in Yeh et al of antioxidant and/or synergistic vitamin C as part of a pain reliever essentially teaches away from the invention, (page 9 of the Final Rejection). Yeh et al



teach that an antioxidant other than a vitamin (A, C or E) may be used (column 2, lines 48-52). Thus, Yeh et al do not teach that vitamin C (or anything else) is required that would supplement nutrition. So, Yeh et al teach away from the invention by teaching that the lack of anything that could function as a nutritional supplement is suitable for its purposes. Portions of a reference teaching away from the claimed invention must be considered, Bausch & Lomb Inc v Barnes-Hind/Hydrocurve, Inc, 796 F2d 443; 230 USPQ 416 (CAFC 1986). Accordingly, no indication of supplementing nutrition would be provided for antioxidant and/or synergistic vitamin C as part of a pain reliever, just as mineral inert ingredients and/or mineral buffering agents are not indicated as supplementing nutrition in major commercial pain relievers. Thus, disclosure of antioxidant that may not function as a nutritional supplement as part of a pharmaceutical essentially teaches away from the invention. So, the prior art teaches away from the invention, which supports a conclusion of nonobviousness, Dow Chemical Co v US, 18 USPQ2d 1657, 1662 (US Claims Ct, 1990).

Furthermore, in general a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the Applicant, In re Gurley 27 F3d 551; 31 USPQ 2d 1130, 1132 (CAFC, 1994). The applied prior art references teach away, as their disclosures of antioxidants are unlikely to be productive of the result of indications indicating supplementing nutrition sought by Applicant's claimed invention, In re Gurley. Accordingly, claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69, 71-84, 86-87 and 91-94 are not prima facie obviousness over the combination of SS Pharmaceutical, Tsunoda, Yeh et al and Krause.

THE APPLIED REFERENCES DO NOT DISCLOSE THE FEATURES OF THE CLAIMED INVENTION OR ANY BENEFIT FROM THE USE THEREOF

The court has held that the absence from the applied references of an explicit requirement of the claims makes the rejection improper, In re Evanega 4 USPQ 2nd 1249 (CAFC, 1987). All of the claims explicitly require a method of providing a unit dose of a discomfort reliever in an enclosure having indications indicating supplementing nutrition. Beneficially, Applicant's invention provides,

for example, indications indicating a percent of a daily value for nutritional supplement in the unit dose and/or instructions for consuming the unit dose for supplementing nutrition. The applied prior art does not disclose a unit dose of a discomfort reliever in an enclosure having indications indicating supplementing nutrition.

The applied medication prior art does not disclose or teach including any amount of antioxidant and/or synergistic vitamins beyond that, which is part of a pharmaceutical medication (cold, menstruation and/or periodontal). Nor does the applied medication prior art disclose or teach any amount of any antioxidant and/or synergistic vitamin for nutrition. Additionally, the applied medication prior art does not disclose a discomfort reliever in an enclosure having indications indicating supplementing nutrition. The applied medication prior art does not disclose indications indicating a daily value for supplementing nutrition for any amount of the antioxidant and/or the synergistic portion of the pharmaceutical. In the applied medication prior art, pharmaceutical antioxidant and/or synergistic vitamins are not disclosed as being provided to supplement nutrition. Nor are they disclosed as providing a daily value for a nutritional supplement. So, one of ordinary skill in the pharmaceutical art would not indicate an antioxidant and/or synergistic vitamin as being provided for supplementing nutrition, just as mineral inert ingredients and/or mineral buffering agents are not indicated as supplementing nutrition in major commercial pain relievers. Thus, the applied prior art references do not disclose or teach a method of enclosing a unit dose of a discomfort reliever in an enclosure having indications indicating supplementing nutrition, as claimed by Appellant. These explicit requirements of the claims are not disclosed by SS Pharmaceutical, Tsunoda, Yeh et al or Krause. SS Pharmaceutical (lines 2-3 of the abstract), Tsunoda (lines 1-3 of the abstract) and Yeh et al (column 2, lines 5 and 31-37) disclose including antioxidant and/or synergistic vitamins as part of a pharmaceutical medication (cold, menstruation and/or periodontal). Krause does not disclose a discomfort reliever. The absence from all of the applied references of these explicit requirements of the claims makes the rejection erroneous and improper, In re Evanega.

Accordingly, the claims are not unpatentable under 35 USC 103 over SS Pharmaceutical in view of Tsunoda, Yeh et al and Krause.

Additionally, the applied prior art does not provide the benefits of the invention. Beneficially, the invention provides the user with an indication of a percent of a daily value for nutritional supplement in the unit dose. With this indication the user has the ability to self regulate consumption of nutritional supplements while alleviating a discomfort.

ALL THE LIMITATIONS OF A CLAIM MUST BE CONSIDERED MEANINGFUL

All of the limitations of a claim must be considered meaningful, Perkin – Elmer Corp. v Westinghouse Elec. Corp. 3 USPQ2d 1321, 1324-25 (Fed. Cir, 1987). Applicant's claims require a method of providing a unit dose of discomfort reliever in an enclosure having indications indicating supplementing nutrition. Beneficially, Applicant's invention provides, for example, indications indicating a nutritional supplement for supplementing nutrition; a percent of a daily value for the nutritional supplement in the unit dose and/or instructions for consuming the unit dose for supplementing nutrition. These features are not disclosed by the applied discomfort reliever prior art. Indicating supplementing nutrition for a unit dose of discomfort reliever is a new and additional feature, which is not disclosed in the applied art. All of the limitations of a claim must be considered meaningful, Perkin – Elmer Corp. The rejection does not meaningfully consider all of the limitations of the claims. Accordingly, the claims are not unpatentable over SS Pharmaceutical Tsunoda, Yeh et al and Krause.

Krause discloses labeling for food (see page 277, last paragraph). Food contains protein, fat, carbohydrate, and has an energy value, see Krause page 279, right column, first paragraph. The disclosure in Krause of food, protein, fat, or carbohydrate, and energy value is not a basis for relieving a discomfort, as is required by Applicant's claims. The applied medication prior art does not disclose food, protein, fat, carbohydrate, or energy values. So, there is no basis for combining it with Krause. The applied medication prior art discloses pharmaceuticals having antioxidant and/or synergistic vitamins, as part of the

pharmaceuticals. Any optimization of these antioxidant and/or synergistic vitamins, as part of the pharmaceuticals disclosed by the applied medication prior art, would be for their antioxidant and/or synergistic functions in the pharmaceuticals. By contrast, Applicant's invention provides, for example, indications indicating a nutritional supplement for supplementing nutrition; a percent of a daily value for the nutritional supplement in the unit dose and/or instructions for consuming the unit dose for supplementing nutrition. The rejection is improper as it does not meaningfully consider all of the limitations of the claims, Perkin – Elmer. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69, 71-84, 86-87 and 91-94 as unpatentable over SS Pharmaceutical, Tsunoda, Yeh et al and Krause is erroneous.

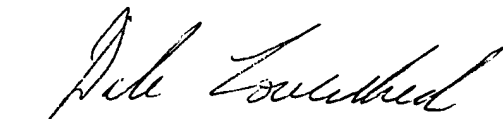
The applied medication prior art discloses pharmaceuticals, which include antioxidant and/or synergistic vitamins, as see Yeh et al, column 2, lines 5 and 31-37. These antioxidant and/or synergistic vitamin(s) are disclosed as part of the pharmaceutical. Disclosure of an antioxidant and/or a synergistic vitamin as part of a pharmaceutical is not a basis for indicating a nutritional supplement is being provided to supplement nutrition, just as mineral inert ingredients and/or mineral buffering agents are not indicated as supplementing nutrition in major commercial pain relievers. The rejection is improper as it does not meaningfully consider all of the limitations of the claims, Perkin – Elmer. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69, 71-84, 86-87 and 91-94 as unpatentable over SS Pharmaceutical, Tsunoda, Yeh et al and Krause is erroneous.

#### TOPICAL TREATMENTS

Yeh et al discloses topical treatment of periodontal disease with a synergistic anti-inflammatory and antioxidant, as see column 1, lines 6-7 and column 2, lines 1-12. Yeh et al does not disclose supplementing nutrition or indicating a daily value for a nutritional supplement. Oral dosage form orally consumable material is not disclosed by Yeh et al. Accordingly, the claims are not unpatentable over SS Pharmaceutical, Tsunoda, Yeh et al and Krause.

The claims are believed to be allowable. Such action is respectfully requested.

Respectfully submitted,

A handwritten signature in cursive script, reading "Dale Lovercheck", written in black ink. The signature is positioned above a horizontal line.

DALE R. LOVERCHECK February 29, 2004

Patent Attorney Reg. No. 28638

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■ high blood pressure, heart or kidney disease, are taking a diuretic, or are over 65 years of age

**Ask a doctor or pharmacist before use if you are**  
 ■ under a doctor's care for any serious condition  
 ■ taking any other product that contains ibuprofen,  
 other pain reliever/fever reducer ■ taking a prescription  
 drug for anticoagulation (blood thinning) ■ taking  
 other drug

**When using this product take with food or milk if stomach upset occurs**

**Stop use and ask a doctor if** ■ an allergic reaction occurs. Seek medical help right away. ■ pain gets worse or lasts more than 10 days ■ fever gets worse or lasts more than 3 days ■ stomach pain or upset gets worse or lasts ■ redness or swelling is present in the painful area ■ any new symptoms appear

**pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.**

Active ingredient (in each caplet)	Purposes
ibuprofen 200 mg	Pain reliever/fever reducer

**Uses** ■ temporarily relieves minor aches and pains due to: ■ headache ■ the common cold ■ toothache ■ muscular aches ■ backache ■ minor pain of arthritis ■ menstrual cramps ■ temporarily reduces fever

## Varminos

**allergy alert:** Ibuprofen may cause a severe allergic reaction which may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock

**Stomach bleeding warning:** Taking more than recommended may cause stomach bleeding.

**Technical warning:** if you consume 3 or more alcoholic drinks every day, ask your doctor whether you should use ibuprofen or other pain relievers/fever reducers.

**do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer.**

ask a doctor before use if you have ■ problems or  
serious side effects from taking pain relievers or fever  
reducers ■ stomach problems that last or come back,  
such as heartburn, upset stomach, or pain ■ ulcers  
bleeding problems

# Advil

**24 Coated Caplets\***  
\*Capsule-Shaped Tablets

## Caplets

## 24 Coated Caplets

Do Not Use - seal under bottle cap, important  
SEALED FOR YOUR PROTECTION. 5 mg tablets

5:52 31.00m

U.S. Patent No. 5,111,111

Appearance of the group Ad...  
is a trademark of Wyman Consumer Products, Inc.

### Directions

- **do not take more than directed**
- **adults and children 12 years and over: take 1 caplet every 4 to 6 hours while symptoms persist**
- **if pain or fever does not respond to 1 caplet, 2 caplets may be used**
- **do not exceed 6 caplets in 24 hours, unless directed by a doctor**
- **the smallest effective dose should be used**
- **children under 12 years: ask a doctor**

**Other Information** ■ read all warnings and directions before use. Keep carton.

■ store at 20-25°C (68-77°F)

• avoid excessive heat 40°C (above 104°F)

**passive inpatients**

[illegible]

**Questions or comments?**  
Call toll-free 1-800-88-ADVIS

# EXHIBIT B

EXP:

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8721790

## Motrin IB Ibuprofen

Caplet-Shaped Tablets

### Drug Facts (continued)

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

#### Directions

- do not take more than 6 caplets in 24 hours
- take 1 caplet every 4 to 6 hours with symptoms persist
- if pain or fever does not respond to 1 caplet, 2 caplets may be used, but do not exceed 6 caplets in 24 hours, unless directed by a doctor
- the smallest effective dose should be used
- ask a doctor

children under 12 years

#### Other Information

- do not use if neck wrap or tell liner seal is broken or missing
- store between 20° - 25°C (68° - 77°F)
- see end panel for lot number and expiration date

### Drug Facts

#### Active Ingredient (in each caplet)

Ibuprofen 200 mg

#### Purposes

- temporarily relieves minor aches and pains due to:
  - headache
  - minor pain of arthritis
  - backache
  - menstrual cramps
- temporarily reduces fever
- temporarily relieves minor aches and pains due to:
  - muscular aches
  - toothache
  - the common cold

#### Warnings

- Allergy alert: Ibuprofen may cause a severe allergic reaction which may include:
  - hives
  - facial swelling
  - asthma (wheezing)
  - shock
- Abdominal warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take Ibuprofen or other pain relievers/fever reducers. Ibuprofen may cause stomach bleeding.
- Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer

### Drug Facts (continued)

Ask a doctor before use if you have:
 

- stomach pain
- problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are:
 

- under a doctor's care for any serious condition
- taking any other product that contains Ibuprofen, naproxen, or any other pain reliever/fever reducer

When using this product give with food or milk, if stomach upset occurs

- Stop use and ask a doctor if:
  - an allergic reaction occurs. Seek medical help right away.
  - pain gets worse or lasts more than 10 days
  - fever gets worse or lasts more than 3 days
  - stomach pain or upset gets worse or lasts
  - redness or swelling is present in the painful area
  - any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use Ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

### Drug Facts (continued)

#### Inactive Ingredients

camellia wax, corn starch, FD&C Yellow #6, hypromellose, iron oxide, polydextrose, polyethylene glycol, silicon dioxide, stearic acid, titanium dioxide

#### Questions or comments?

Call toll-free 1-800-862-5357

McNeil Consumer & Specialty Pharmaceuticals  
DIVISION OF MCNEIL-PPC, INC.  
FORT WASHINGTON, PA 19004 USA  
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www.motrin.com



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- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

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- under a doctor's care for any serious condition
- taking any other drug

**Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.**

- do not exceed 2 tablets in any 8- to 12-hour period
- do not exceed 3 tablets in a 24-hour period

● DO NOT take more than 1 tablet unless directed by a doctor



## EXHIBIT D

# ALEVE®

naproxen sodium tablets, 220 mg  
Pain reliever / fever reducer

Consumer labeling leaflet for ALEVE. Please save this for future use.  
Only selected information is listed on the bottle label.  
Therefore, you should keep this sheet for future reference.  
ALEVE Tablets, Caplets\* or Gelcaps\*\* naproxen sodium tablets, USP

### Drug Facts

#### Active Ingredient (in each tablet, caplet\*, gelcap\*\*)

Naproxen sodium 220 mg (naproxen 200 mg)

#### Purposes

Pain reliever/fever reducer

#### Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - muscular aches
  - minor pain of arthritis
  - toothache
  - backache
  - the common cold
  - menstrual cramps
- temporarily reduces fever

#### Warnings

**Allergy alert:** Naproxen sodium may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

**Alcohol warning:** If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take naproxen sodium or other pain relievers/fever reducers. Naproxen sodium may cause stomach bleeding.

**Do not use** if you have ever had an allergic reaction to any other pain reliever/fever reducer.

**Ask a doctor before use** if you have ever had serious side effects from any pain reliever/fever reducer.

**Ask a doctor or pharmacist before use** if you are:

- under a doctor's care for any serious condition

- taking any other drug
- taking any other product that contains naproxen sodium, or any other pain reliever/fever reducer

**Stop use and ask a doctor if:**

- an allergic reaction occurs. Seek medical help right away.
- fever gets worse or lasts more than 3 days
- it feels like the pill is stuck in your throat
- stomach pain occurs or lasts, even if symptoms are mild
- any new symptoms appear
- pain gets worse or lasts more than 10 days
- you have difficulty swallowing
- you develop heartburn
- redness or swelling is present in the painful area

**If pregnant or breast-feeding,** ask a health professional before use. It is especially important not to use naproxen sodium during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

#### Directions

- do not take more than directed
- drink a full glass of water with each dose

Adults and children 12 years and older

- take 1 tablet (caplet\*, gelcap\*\*) every 8 to 12 hours while symptoms last
- for the first dose you may take 2 tablets (caplets\*, gelcaps\*\*) within the first hour
- the smallest effective dose should be used
- do not exceed 2 tablets (caplets\*, gelcaps\*\*) in any 8- to 12-hour period
- do not exceed 3 tablets (caplets\*, gelcaps\*\*) in a 24-hour period

Adults over 65 years

- do not take more than 1 tablet (caplet\*, gelcap\*\*) every 12 hours unless directed by a doctor

Children under 12 years

- ask a doctor

#### Other information

- each tablet (caplet\*, gelcap\*\*) contains sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

**Inactive ingredients** (tablet, caplet\*) FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

**Inactive ingredients** (gelcap\*\*) D&C yellow #10 aluminum lake, edetate disodium, edible ink, FD&C blue #1, FD&C yellow #6 aluminum lake, gelatin, glycerin, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, stearic acid, talc, titanium dioxide

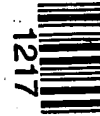
**Questions or comments?** 1-800-395-0689 or [www.aleve.com](http://www.aleve.com)

\*capsule-shaped tablet(s)

\*\*gelatin coated capsule-shaped tablet(s)

For instructions on how to open the bottle and how to open and read the bottle label, please see other side. B-R LLC

Distributed by: Bayer HealthCare LLC  
Consumer Care Division  
P.O. Box 18110  
Morrowtown, NJ 07962-1910 USA



# EXHIBIT E

Drug Facts	Active Ingredient (in each caplet)	Purpose
<b>Uses</b> temporarily relieves minor aches and pains due to:	Acetaminophen 500 mg...	Pain reliever/fever reducer
<ul style="list-style-type: none"> <li>headache</li> <li>backache</li> <li>the common cold</li> <li>menstrual cramps</li> <li>temporarily reduces fever</li> </ul>	<ul style="list-style-type: none"> <li>muscular aches</li> <li>arthritis</li> <li>toothache</li> </ul>	
<b>Warnings</b>		
<p>Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers.</p> <p>Acetaminophen may cause liver damage.</p> <p>Do not use it with any other product containing acetaminophen.</p> <p>Stop use and ask a doctor if:</p> <ul style="list-style-type: none"> <li>new symptoms occur</li> <li>redness or swelling is present</li> <li>pain gets worse or lasts for more than 10 days</li> <li>fever gets worse or lasts for more than 3 days</li> </ul> <p>If pregnant or breast-feeding, ask a health professional before use.</p>		

NEW LABEL INFORMATION

## Extra Strength TYLENOL®

Contains Acetaminophen

Pain Reliever - Fever Reducer

24 CAPLETS  
500 mg each

Caplets

NEW LABEL INFORMATION

## Extra Strength TYLENOL®

Contains Acetaminophen

Pain Reliever - Fever Reducer

24 CAPLETS  
500 mg each

Caplets

<b>Drug Facts (continued)</b>	<b>Directions</b>	<b>Other Information</b>
<p>Keep out of reach of children.</p> <p>Overdose warning: Taking more than the recommended dose (overdose) could cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p>	<p>Do not take more than directed (see overdose warning).</p> <p>Adults and children 12 years and over: Take 2 caplets every 4 to 6 hours as needed. Do not take more than 8 caplets in 24 hours.</p> <p>Children under 12 years: Do not use this adult Extra Strength product in children under 12 years of age. This will provide more than the recommended dose (overdose) of TYLENOL® and could cause serious health problems.</p>	<p><b>Other Information</b></p> <p>Do not use if carton is opened or neck wrap or foil inner seal imprinted with "Safety Sealer" is broken or missing.</p> <p>Store at room temperature.</p>

<b>Drug Facts (continued)</b>
<p>See end panel for lot number and expiration date.</p> <p><b>Inactive Ingredients</b> cellulose, corn starch, FD&amp;C red #40, hypromellose, magnesium stearate, polyethylene glycol, sodium starch glycolate, titanium dioxide.</p> <p><b>Questions or comments?</b> call toll-free 1-877-TYLENOL (1-877-895-3665)</p> <p>Distributed by: McNeil Consumer &amp; Specialty Pharmaceuticals DIVISION OF MCNEIL-PPC, INC. FORT WASHINGTON, PA 19034 USA Visit us at <a href="http://www.tylenol.com">www.tylenol.com</a> or call toll-free 1-877-TYLENOL (1-877-895-3665)</p>




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CH 6

# EXHIBIT F



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**Drug Facts (continued)**

**Stop use and ask a doctor if**

- new symptoms occur
- symptoms do not get better or worsen
- painful area is red or swollen
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days


**If pregnant or breast-feeding, ask a health professional before use.**

**Keep out of reach of children.**

**Overdose warning:** Taking more than the recommended dose can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

- do not use more than directed (see overdose warning)
- adults and children 12 years of age and over: take 2 tablets every 6 hours; not more than 8 tablets in 24 hours
- children under 12 years of age: ask a doctor



1158033A1

ASPIRIN FREE

**Excedrin**

TENSION HEADACHE

**Drug Facts (continued)**

**Other information**

- store at room temperature
- read all product information before using. Keep this box for important information.

**Inactive ingredients:** benzoic acid, corn starch, croscarmellose sodium, FD&C Blue #1, FD&C Red #40, FD&C Yellow #5, gelatin, glycerin, hypromellose, magnesium stearate, methylparaben, microcrystalline cellulose, mineral oil, polyethylene glycol, polyethylene glycol, propylene glycol, propylene glycol, simethicone emulsion, sodium monolaurate, stearic acid, titanium dioxide

**They contain these ingredients:**

**Questions or comments?**

1-800-448-7146

ASPIRIN FREE

**Excedrin**

TENSION HEADACHE

ASPIRIN FREE

**Excedrin**

TENSION HEADACHE

Acetaminophen and Caffeine

24 GELTABS EASY TO SWALLOW

ASPIRIN FREE

**Excedrin**

TENSION HEADACHE

Acetaminophen and Caffeine

24 GELTABS EASY TO SWALLOW

**Drug Facts**

**Active ingredients (in each tablet):** Acetaminophen 500 mg, Caffeine 65 mg (formulated with 65 mg caffeine)

**Purpose:** Pain reliever

**Uses:** Temporarily relieves minor aches and pains due to:

- headache
- muscular aches

**Warnings:**

**Alcohol warning:** If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers.

**Acetaminophen warning:** Acetaminophen may cause liver damage. The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and occasionally, rapid heart beat.

**Do not use:**

- with any other products containing acetaminophen, taking more than directed may cause liver damage.

ASPIRIN FREE

**Excedrin**

TENSION HEADACHE

Acetaminophen and Caffeine

24 GELTABS EASY TO SWALLOW

